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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

on an interoperable, cross-border identification and authentication mechanism for natural persons, health professionals and healthcare providers for the purposes of the cross-border exchange of personal electronic health data

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

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on an interoperable, cross-border identification and authentication mechanism for natural persons, health professionals and healthcare providers for the purposes of the cross-border exchange of personal electronic health data

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847⁽¹⁾, and in particular Article 16, paragraph (2) thereof,

Whereas:

- (1) Regulation (EU) 2025/327 seeks to improve the cross-border exchange of personal electronic health data to ensure continuity of healthcare. A growing number of natural persons living in one Member State of the Union receive healthcare in another Member State and their electronic health records are increasingly dispersed among the healthcare systems of different Member States, which use different identifiers to identify natural persons and their records. Similarly, the means for identifying health professionals and healthcare providers differ among Member States. To facilitate the exchange of personal electronic health data in a cross-border context through the MyHealth@EU platform referred to in Article 23(1) of Regulation (EU) 2025/327, it is necessary to identify the actors involved in the exchange and match the identities of natural persons to their electronic health records. It is therefore necessary to determine the requirements for an interoperable, cross-border identification and authentication mechanism for natural persons and health professionals and healthcare providers.
- (2) An efficient and non-intrusive way to locate personal electronic health data is using the identification data assigned to natural persons in the national health system of their Member State of affiliation. Since the identification data used in the various Member States differ, it is appropriate to require Member States to determine the identification data that are to be used to identify natural persons for the purposes of the cross-border exchange of personal electronic health data and to notify them to the Commission in view of their publication. The requirements for cross-border identification and authentication mechanism are to comply with Regulation (EU) No 910/2014 of the European Parliament and of the Council². Furthermore, in accordance with Article 5f(1) and (2) of Regulation (EU) No 910/2014, systems provided by public sector bodies and online services provided by private relying parties that require electronic

¹ OJ L, 2025/327, 5.3.2025, ELI: <http://data.europa.eu/eli/reg/2025/327/oj>.

² Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC (OJ L 257, 28.8.2014, p. 73).

identification or authentication for access to online services are to accept European Digital Identity Wallets as referred to in Article 5a of Regulation (EU) 910/2014, where natural persons choose to use them. In order to facilitate the cross-border exchange of personal electronic health data, natural persons should be able to request from their Member State of affiliation the issuance of their identification data for cross-border healthcare in the form of an electronic attestation of healthcare attributes to be stored in their European Digital Identity Wallet. Furthermore, natural persons should be able to share their healthcare attributes with health professionals and healthcare providers established in another Member State to enable the health professional or healthcare provider to locate the personal electronic health data at their source.

- (3) Before initiating or requesting the cross-border exchange of personal electronic health data of a natural person through MyHealth@EU, health professionals and healthcare providers should be identified and authenticated, and the natural person concerned should be identified. Such identification and authentication are necessary to ensure the secure processing of personal electronic health data, to prevent unauthorised access, and to enable the provision of information on data accesses as required by Article 9 of Regulation (EU) 2025/327. Where electronic identification means are used for those purposes, they should provide at least the assurance level ‘substantial’ referred to in Article 8(2), point (b), of Regulation (EU) No 910/2014. The European Digital Identity Wallet provides the assurance level ‘high’ referred to in Article 8(2), point (c), of that Regulation. From 26 March 2030 onwards, all electronic identification means used for the identification of natural persons whose personal electronic health data are exchanged through MyHealth@EU should provide the assurance level ‘high’. From 26 March 2032 onwards, all electronic identification means used for the identification and authentication of health professionals and healthcare providers for the purposes of such exchanges should provide the assurance level ‘high’. This phased approach serves to allow sufficient time for the full rollout of electronic identification means in the Member States.
- (4) Where Member States use an electronic identification means that has not been notified to the Commission pursuant to Regulation (EU) No 910/2014, the assurance level ‘high’ of that means should be confirmed by a conformity assessment body referred to in Article 2, point (13), of Regulation (EC) No 765/2008 or an equivalent body. This requirement should apply irrespective of whether the cross-border exchange concerns the transmission of data to, or the reception of data from, another Member State.
- (5) The national contact point for digital health that requests the cross-border exchange of personal electronic health data of a natural person should communicate the identification data of the health professional or healthcare provider to the national contact point for digital health of the Member State to which the request is sent.
- (6) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council³ and delivered an opinion on XX XX 2026.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the committee established by Article 98(1) of Regulation (EU) 2025/327.

³ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39, ELI: <http://data.europa.eu/eli/reg/2018/1725/oj>).

HAS ADOPTED THIS REGULATION:

Article 1
Subject matter

This Regulation lays down the requirements for the interoperable, cross-border identification and authentication mechanism for natural persons, health professionals and healthcare providers for the purposes of cross-border exchange of electronic health data.

Article 2
Definitions

For the purposes of this Regulation the following shall definitions apply:

- (1) ‘healthcare attribute’ means an attribute that is used for the identification of a natural person for the purposes of cross-border exchange of electronic health data;
- (2) ‘attribute’ means attribute as defined in Article 3, point (43), of Regulation (EU) 910/2014;
- (3) ‘electronic attestation of attributes’ means electronic attestation of attribute as defined in Article 3, point (44), of Regulation (EU) 910/2014;
- (4) ‘European Digital Identity Wallet’ means European Digital Identity Wallet as defined in Article 3, point (42), of Regulation (EU) 910/2014;
- (5) ‘authentication’ means authentication as defined in Article 3, point (5), of Regulation (EU) 910/2014.

Article 3
National sets of healthcare attributes of natural persons

1. Each Member State shall determine a set of healthcare attributes to be used to verify the identity of natural persons in connection with their electronic health records for the purposes of the cross-border exchange of their personal electronic health data.
2. Each Member State shall notify its set of healthcare attributes to the Commission by 26 March 2028. The Commission shall publish the Member States’ sets of healthcare attributes.
3. Upon request by a natural person, the competent authority in the Member State of affiliation of that person shall issue the healthcare attributes of that natural person in the form of an electronic attestation of attributes in accordance with the set of healthcare attributes defined pursuant to paragraph 1 to that person’s European Digital Identity Wallet.

Article 4
Identification and authentication of natural persons for the cross-border exchange of personal electronic health data

1. Before requesting the exchange of personal electronic health data of a natural person through MyHealth@EU, the health professional or healthcare provider shall identify and authenticate that natural person. For that purpose, the health professional or

healthcare provider may collect the healthcare attributes of the Member State of affiliation of the natural person.

2. Where a health professional or healthcare provider requests the exchange of personal electronic health data of a natural person through MyHealth@EU following a natural person's request submitted online, that health professional or healthcare provider shall identify and authenticate that natural person using electronic identification means issued in accordance with Regulation (EU) No 910/2014. The electronic identification means shall comply with the requirements of Regulation (EU) 910/2014 and provide an assurance level that is at least substantial as referred to in Article 8(2), point (b), of Regulation (EU) No 910/2014. From 26 March 2030 the electronic identification means shall provide the assurance level high, referred to in Article 8(2), point (c), of the same Regulation.
3. Where a natural person has been authorised by another natural person to access their personal electronic health data, or part thereof, on their behalf or acts as the legal representative of another natural person in accordance with Article 4(2) of Regulation (EU) 2025/327, the health professional or healthcare provider shall identify that natural person and verify that the authorised natural person or the legal representative satisfy the necessary requirements to act in that capacity.

Article 5

Requirements for the cross-border exchange of healthcare attributes of natural persons

1. Where a national contact point for digital health requests the exchange of personal electronic health data of a natural person from or to another national contact point for digital health, the first national contact point shall submit the healthcare attributes of the natural person's Member State of affiliation to the second national contact point.
2. The health professional or healthcare provider requesting the exchange of personal electronic health data pursuant to Article 4(1), regardless of whether the natural person's request is made in-person or online, shall accept the healthcare attributes provided in the form of an electronic attestation of attributes using a European Digital Identity Wallet.
3. Where the identification means used do not provide the healthcare attributes in full, the health professional or healthcare provider requesting the exchange of personal electronic health data may request additional information from the natural person to complete the set of healthcare attributes of the Member State of affiliation of the natural person.

Article 6

Identification, authentication and authorisation of health professionals and healthcare providers for the cross-border exchange of personal electronic health data

1. Each Member State shall list the entity or entities responsible for identifying, authenticating and authorising the health professional or healthcare provider requesting the cross-border exchange of personal electronic health data.
2. Before requesting the cross-border exchange of personal electronic health data through MyHealth@EU, the entity or entities referred to in paragraph 1 shall identify, authenticate and authorise the health professional or healthcare provider requesting that exchange.

3. The entity or entities referred to in paragraph 1 shall identify and authenticate the health professional or healthcare provider using electronic authentication means that provides at least the assurance level substantial referred to in Article 8(2), point (b), of Regulation (EU) No 910/2014. From 26 March 2032, the electronic authentication means shall provide the assurance level high referred to in Article 8(2), point (c), of that Regulation.

Article 7

Requirements for the exchange of the health professional and healthcare provider identification data

When the health professional or healthcare provider requests the cross-border exchange of personal electronic health data through MyHealth@EU, the national contact point for digital health competent for that health professional or healthcare provider shall communicate to the national contact point for digital health receiving the request the identification data of the health professional or healthcare provider. The identification data shall comply with the technical specifications set out in the Annex.

Article 8

Mechanism for the exchange of identification data through MyHealth@EU

The mechanism for the exchange of identification data through MyHealth@EU shall support:

- a) the notification and the publication of the sets of healthcare attributes referred to in Article 3(2) of this Regulation;
- b) the exchange of the healthcare attributes between national contact points for digital health described in Article 5(1);
- c) the exchange of the identification data of the health professional or healthcare provider between national contact points for digital health described in Article 7.

Article 9

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

It shall apply from 26 March 2027.

However, Article 3(3) and Article 5(2) shall apply from 26 March 2029.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN